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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,699	05/03/2007	Kazuhiro Abe	HNS00003(US) TYCN 0003.14	5050
54964	7590	05/27/2010	EXAMINER	
TYCO HEALTHCARE - EDWARD S. JARMOLOWICZ			VU, QUYNH-NHU HOANG	
15 HAMPSHIRE STREET			ART UNIT	PAPER NUMBER
MANSFIELD, MA 02048			3763	
MAIL DATE		DELIVERY MODE		
05/27/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,699	<b>Applicant(s)</b> ABE ET AL.
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 August 2006.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement (PTO-1448)  
Paper No(s)/Mail Date 11/14/06; 04/10/07; 09/07/07 & 05/15/09
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 5-8, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (US 2003/0229334) in view of Shermeta (US 3,915,171).**

Suzuki discloses an infection-preventing sheath gastrostomy catheter kit comprising: a gastrostomy catheter 20 including a flexible, hollow tube, a deformable intragastric retainer 23 is made foldable and positioned at the trailing end of said tube, and a tapered member 22 positioned at the leading end of said tube for retaining the leading end portion of a guide wire 15 inserted from the leading end hole thereof; and an infection-preventing sheath 11 including a flexible, hollow tubular body, and a socket member 13 positioned at the trailing end of said tubular body for retaining said intragastric retainer, to removably sheathe said gastrostomy catheter.

Suzuki does not disclose the tube including reinforcement.

Shermeta discloses the gastrostomy catheter 10 including reinforcement 15.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Suzuki with reinforcement, as taught by Shermeta, in order to prevent the kinking, collapse or the pinching closed of the tubular conduit.

**Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Shermeta and further in view of Foster, Jr (US 4,485,805).**

Regarding claim 2, Suzuki in view of Shermeta discloses the invention substantially as claimed.

See rejection of claim 1 above. Suzuki further discloses a tapered member 22.

Suzuki in view of Shermeta does not disclose a housing sheath for deforming and housing the intragastric retainer.

Foster suggests a housing sheath 17 for deforming and housing of the foldable balloon 11 while inserting into the body.

Since the retainer 23 of Suzuki is expandable and foldable like as balloon 11 of Foster, therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Suzuki in view of Shermeta with a housing sheath, as taught by Foster, for the benefits of easy insertion the retainer into the hollow tube and prevent the premature expandable in time.

**Regarding claim 4,** Foster is silent that the housing sheath 17 is made of flexible. However, it is well known in the art the sheath made of flexible characteristic for easy guiding the balloon moving through the small hollow tube.

**Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Shermeta, Foster and further in view of Bryan et al. (US 5,582,165).**

Suzuki in view of Shermeta and Foster discloses the invention substantially as claimed. Suzuki in view of Shermeta and Foster an does not disclose a hook member disposed near the leading end portion of its inner wall.

Bryan teaches that a hook member/connector 25 disposed near the leading end portion of its inner wall of the tube/sheath 28. See Figs. 13-14.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Suzuki in view of Shermeta and Foster with a hook member, as taught by Bryan, for the benefit of keeping the housing sheath maintain inside the tube while the expandable/foldable retainer moving out easily.

**Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Shermeta and further in view of Aase (EP 0420486, cited from IDS).**

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Suzuki in view of Shermeta discloses the invention substantially as claimed. Shermeta discloses the reinforcement in the form of spring (filament). Shermeta does not disclose the spring/filaments made of stainless steel; wherein the diameter of spring/filaments about 0.2 mm.

Aase discloses the catheter comprising reinforcement 40, 44 made of stainless steel, col. 4, lines 10-12; and the diameter of the reinforcing strand of about 0.001 inch (~0.0254mm) to 0.002 inch (0.0508 mm), col. 4, lines 16-18.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Suzuki in view of Shermeta with reinforcement made of stainless steel, as taught by Aase, in order to enhance the tensile strength and flexibility to prevent the kinking, collapse or the pinching closed of the tubular conduit.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/  
Examiner, Art Unit 3763